UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,376	01/25/2007	Zoran Ham	33609US-PCT 64653.US	7293

83721 7590 05/05/2009

Lek (Slovenia) - LUEDEKA, NEELY & GRAHAM, P.C.
P.O. BOX 1871
Knoxville, TN 37901

EXAMINER	
YEAGER, RAYMOND P	

ART UNIT	PAPER NUMBER
1619	

MAIL DATE	DELIVERY MODE
05/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,376	HAM, ZORAN	
	Examiner	Art Unit	
	RAYMOND P. YEAGER	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-10* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Application 10/587,376 (07/26/2006) is a national stage entry of PCT/EP2005/000875 (01/28/2005) per 35 USC 371 and claims foreign priority to SLOVENIA P-2004400032 (01/29/2004) per 35 USC 119. Claims 1 to 10 are pending.

.

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1 to 5, drawn to *tamsulosin hydrochloride*.

Group II, claim(s) 6 to 9, drawn to *a process for the preparation of the amorphous form of tamsulosin hydrochloride*.

Group III, claim(s) 10, drawn to *a pharmaceutical composition*.

2. As set forth in Rule 13.1 of the Patent Cooperation Treaty (PCT), "the international application shall relate to one invention only or to a group of inventions so linked as to forma single general inventive concept." Moreover, as stated in PCT rule 13.2, "Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features." Furthermore, Rule 13.2

defines "special technical features" as "those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art"

3. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The special technical feature of Group I is the *amorphous form of tamsulosin hydrochloride*. The *amorphous form of tamsulosin hydrochloride* of claim 1 does not present a contribution over the prior art. As disclosed in Miyazawa et al, 2001 (*Current Therapeutic Research* Vol. 62(9)), in view of US Patent 6,395,300 (Publication date: 05/28/2002), hereafter referred to as the '300 patent, the *amorphous form of tamsulosin hydrochloride* of instant claim 1 lacks an inventive step.

Instant claim 1: "*Tamsulosin hydrochloride, ((R)-5-(2-(2-(2-ethoxyphenoxy)ethylamino)propyl-2-methoxybenzenesulphonamide) hydrochloride, in the amorphous form.*"

- Miyazawa et al, 2001 teaches tamsulosin hydrochloride is a potent α1-adrenergic receptor agonist for use in benign prostatic hyperplasia (page 604, paragraph 1, lines 1-5). The prior art teachings of Miyazawa et al, 2001 differ from the claimed invention as follows: Miyazawa et al, 2001 does not disclose an amorphous form of tamsulosin hydrochloride. However, the '300 patent teaches all the limitations that are deficient in Miyazawa et al, 2001: The '300 patent discloses a method for producing drugs in a crystalline state, an amorphous state, or mixtures thereof depending on how droplets

are dried and the excipients present (column 12, lines 42-45) wherein the preferred drugs include tamsulosin hydrochloride (column 7, lines 45-64). It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the tamsulosin hydrochloride of Miyazawa et al, 2001 with the amorphous form of the '300 patent because the '300 patent provides a method which enhances the dissolution rate of the drug in aqueous biological fluids (column 3, lines 41-46). A person of ordinary skill in the art would have been motivated to do so because the '300 patent provides a method to overcome a rate-limiting step to attain therapeutically effective drug doses (column 1, lines 17-19). A person of ordinary skill in the art would reasonably have expected to be successful because the '300 patent provides for a method of making formulations of low solubility drugs to enhance their rate of dissolution (column 1, lines 11-14).

As such, Group I does not share a special technical feature with the instant claims of Group II. Therefore, the claims are not so linked with the meaning of PCT Rule 13.2 so as to form a single inventive concept, and unity between Groups I-II is broken.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND P. YEAGER whose telephone number is (571)270-7681. The examiner can normally be reached on Mon - Fri 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0847. The fax phone

number for the organization where this application or proceeding is assigned is (571) 272-8373.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.P.Y.

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615